I. REMARKS

First, applicants extend their thanks to the Examiner and his supervisor for the in-person interview conducted August 19, 2009. The claims presented herein are identical to those discussed in the in-person interview except for new claims 45 and 46. As such, and as discussed in the interview, the presently pending claims are patentable over the cited Montague et al. reference.

Upon entry of the foregoing amendment, claims 1-21 and 43-46 are pending in the present application. Claims 22-42 were previously cancelled.

Claim 1 is currently amended. As discussed in the in-person interview, basis for this amendment may be found throughout the specification as filed. The active ingredient "ciclesonide" is the "sole active ingredient" specified in the entire specification. No other active ingredients are disclosed. Further, applicants respectfully point out that ciclesonide is the "sole active ingredient" present in the formulation outlined in Example 1 on page 8 of the present specification.

Further, applicants respectfully refer to the conversations conducted between the examiner and the quality control examiner. During those conversations, examiner indicated that the quality control examiner indicated that the phrase "as the sole active ingredient" indeed has sufficient written description in the present specification under 35 U.S.C. §112, 1st paragraph, and thus, would not present new matter.

New claims 45 and 46 have been introduced. Basis for these new claims may be found at page 6, 5th full paragraph of the present specification.

Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

It is believed this amendment does not introduce new matter and entry is respectfully requested.

II. REJECTION UNDER 35 USC § 103(a)

A. REJECTION OF CLAIMS 1-21, 43 AND 44

At page 2 of the Official Action, the Examiner has rejected claims 1-21 and 43-44 under 35 USC § 103(a) as being unpatentable over Montague et al. (US 2004/0266869).

RESPONSE

The rejection is respectfully traversed. The Examiner has not established a prima facie case of obviousness against the presently pending claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, there must be some motivation or teaching in the references cited by the Examiner to combine the separate elements taught in the separate references. As the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more

than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *See KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 at 417-418. Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Presently pending claim 1 is directed to a method for treating a respiratory disease in a patient, which patient is a child and the method comprises administering to the patient a dose of a composition containing ciclesonide as the sole active ingredient, or a pharmaceutically acceptable salt thereof, wherein the

dose of the composition comprises ciclesonide in an amount of from 20 to 200 µg. (emphasis added)

In contrast to the presently pending claims, Montague et al. teaches only a combination therapy of anticholinesterase drugs and ciclesonide. There is no teaching whatsoever in the Montague et al. reference that would motivate the skilled artisan to only use ciclesonide in their method. See [0002] which states, in relevant part,

> "The present invention relates to novel pharmaceutical compositions based on anticholinergics and ciclesonide, processes for preparing them and their use in the treatment of respiratory diseases."

See also [0003] which states, in relevant part:

> "Surprisingly, an unexpectedly beneficial therapeutic effect, particularly a synergistic effect can be observed in the treatment of inflammatory or obstructive diseases of the respiratory tract if one or more anticholinergics are used together with the corticosteroid ciclesonide. In view of this synergistic effect the pharmaceutical combinations according to the invention can be used in smaller doses than would be the case with the individual compounds used in monotherapy in the usual way. This reduces unwanted side effects such as may occur when corticosteroids are administered, for example."

As such, the Montague et al. reference actually teaches away from using only ciclesonide per the teaching in [0003] because of the alleged unwanted side

effects by administering corticosteroids, presumably as the sole active ingredients.

Further, the Montague et al. reference, as conceded by the Examiner at page 4 of the Official Action, "does not anticipate wherein the patient is a child...". As stated before, the presently pending claims are directed to the treatment of a child.

Thus, the Montague et al. reference cited by the Examiner cannot possibly render the presently pending claims obvious. As outlined above, the reference of record contains absolutely no teaching regarding using ciclesonide as the sole active ingredient to treat a respiratory disease in a child patient.

Therefore, the Montague et al. reference does not "teach or suggest all the limitations of the claims" as required by *In re Wilson*. As such, the presently rejected claims are unobvious over the cited references and withdrawal of this rejection is respectfully requested.

III. CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

Joshua B. Goldberg
Registration No. 44,126
Sheldon M. McGee
Registration No. 50,454
Customer No. 34375

Date:August 26, 2009
THE NATH LAW GROUP
112 South West Street
Alexandria, Virginia 22314
Tel: (703) 548-6284
Fax: (703) 683-8396
JBG/SMM/ROA.doc